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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,158	01/30/2007	Yoshinori Watanabe	4439-4043	9153

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1652	

NOTIFICATION DATE	DELIVERY MODE
04/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,158	WATANABE, YOSHINORI	
	Examiner	Art Unit	
	ROBERT B. MONDESI	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 23, 2007* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 7-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *June 30, 2006 and June 5, 2007* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to restriction requirement

Applicants' election with traverse of Invention of Group II, Claims 5-6, 11-12, 17-18, and 23-24 and the further election of SEQ ID NO:2 in amendment, filed November 23, 2007 is acknowledged. The traversal is on the ground(s) that there is no search burden with regards to the patentably distinct inventions of the instant application. This is not found persuasive because

The search for the Groups would each require the search of the extensive sequence database followed by the analysis of the enormous results that accumulate after the search. This would impose a serious burden on the Examiner. Advances over the past five-ten years in automated sequencing polynucleotide/polypeptide characterization techniques have made such activities routine. The entire genome of several organisms, including humans, has been determined and deposited into nucleotide and polypeptide sequence databases. The advances in nucleic acid and polypeptide sequencing techniques have also lead to the exponential growth in the size of nucleic acid and polypeptide sequence databases and an increase in the number and complexity of such databases. For example the GenBank® database in 1996 contained 1,021,211 nucleotide sequences. In 2000 the database contained 10,106,023 nucleotide sequences, about a seventeen-fold increase in the number of nucleotides and about a tenfold increase in the number of sequences. In February 2006, the GenBank database contained 59,750,386,305 bases in 54,584,635 sequence records or about a ninety-one-fold increase in the number of nucleotides and about a fifty-four-

fold increase in the number of sequences. These factors are responsible for exacerbating the search and examination burden faced by the Office with respect to polynucleotide or polypeptide inventions claimed and described in currently filed applications. It now requires significantly more computational time to run individual nucleotide or polypeptide sequence searches for examination purposes than in 1996, and there is significantly more sequence search results and pertinent prior art to consider. In addition, it currently takes more Office resources to correlate the claimed polynucleotide/polypeptide with the polynucleotide/polypeptide as defined in the prior art because it is increasingly common for both patent applicants and prior art references to describe a polynucleotide/polypeptide molecule in different ways.

Therefore the requirement is still deemed proper and is made FINAL.

Status of the claims

Claims 1-27 are pending. **Claims 1-4 and 7-27 (claims 11-12, 17-18 and 23-24 are not drawn to SEQ ID NO: 2)** are withdrawn for pertaining to nonelected subject matter. **Claims 5-6** are presently under examination.

Priority

The current application filed on January 30, 2007 is a 371 of PCT/JP04/17428 filed on 11/24/2004, which in turn claims priority to foreign application, JAPAN 2003-401943 filed on 12/01/2003 JAPAN 2004-279450 filed on 09/27/2004. A certified copy of foreign document JAPAN 2003-401943 and JAPAN 2004-279450 has been provided.

Drawings

Drawings filed May 31, 2006 have been accepted.

Information Disclosure Statement

The IDS filed June 30, 2006 and June 5, 2007 have been received and are signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

The disclosure is objected to because of the following reason:

Examiner would like to point out that there is no information with regards to SEQ ID NO: of the nucleic acid sequences present in Figure 9, in the Brief Description of the Drawings for the mentioned Figure 9. If the Drawings contain amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2) then the Brief Description of the Drawings needs to state the SEQ ID NO: for the nucleotide and/or amino acid sequences. Unless the appropriate SEQ ID NO: accompanies the nucleotide and/or amino acid sequences in the actual Drawing sheet.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is drawn to functional derivatives/natural variant of SEQ ID NO: 2. The claim does not require that the polypeptide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claims are drawn to a genus of polypeptides that is defined by an unclear functional relationship to SEQ ID NO: 2. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is the fact that the proteins have regulatory activity of chromosome segregation. The specification does not identify any particular portion of the structure that must be characteristics of the claimed genus are not described. The only adequately described species is SEQ ID NO: 2 and no active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, “applicant must convey with reasonable clarity to those skilled in the a14 that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, whatever is now claimed." (See page 1117.) The specification does

not it clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers* v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF' s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U. S.C. 112, first paragraph. Applicant is reminded that *Vas-cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The polypeptide as claimed, has an amino

acid sequence duplicative of that of a protein which possesses the biological and functional properties of a naturally occurring polypeptide and therefore does not constitute patentable subject matter absent recitation of "isolated and purified" in the preamble.

See *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant*, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by Cao et al., US Patent Application No.: US 2003/0233675.

Claim 6 is drawn to a protein consisting of an amino acid sequence where one or several amino acids are deleted, replaced or added in an amino acid sequence shown in SEQ ID NO: 2. Cao et al., (US 2003/0233675, SEQ ID NO: 2386) disclose such a sequence, see STIC sequence alignment below/next page:

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  Query Match             98.8%;  Score 1627.5;  DB 4;  Length 340;
  Best Local Similarity   93.8%;  Pred. No. 4.3e-108;
  Matches  319;  Conservative    0;  Mismatches    0;  Indels   21;  Gaps    1;

Qy          1 MNFQFINSNINNEDKLPMESLKKKFLKQNREIIK----------------------INTQL 39
              |||||||||||||||||||||||||||||||||||                      |||||
Db          1 MNFQFINSNINNEDKLPMESLKKKFLKQNREIIKVRSKYTIFESLVVNNKHLTFRINTQL 60

Qy         40 SIKIRESENEIQDLIQENFTLKSYLVKLEARFRNQSQTEDLLKNFFPEIQTIHKKISQVQ 99
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 SIKIRESENEIQDLIQENFTLKSYLVKLEARFRNQSQTEDLLKNFFPEIQTIHKKISQVQ 120

Qy        100 SLLKIIEKKCSSDFLEANVKSQFTTCENKDSKEDYQILHNKRLEYVSFNDELKSLEIGQP 159
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SLLKIIEKKCSSDFLEANVKSQFTTCENKDSKEDYQILHNKRLEYVSFNDELKSLEIGQP 180

Qy        160 LYCFQDFQKKVHGPPALSEKPGKCILKDKTNAHVNKIPQDEVNYSLPQKNITIFSKELKE 219
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 LYCFQDFQKKVHGPPALSEKPGKCILKDKTNAHVNKIPQDEVNYSLPQKNITIFSKELKE 240

Qy        220 NEFESINEGETEEEKAKTSNVCVCIPCKSAEQITDLKGQAIGDSSPCDFEESQPRINGRE 279
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 NEFESINEGETEEEKAKTSNVCVCIPCKSAEQITDLKGQAIGDSSPCDFEESQPRINGRE 300

Qy        280 KLRRSVKVINYAIPSLRTKLRRDFDLPSDRKRKRHPRGKA 319
              |||||||||||||||||||||||||||||||||||||||||
Db        301 KLRRSVKVINYAIPSLRTKLRRDFDLPSDRKRKRHPRGKA 340
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Thus Cao et al. teach all the elements of **claim 6** and this claim is anticipated under 35 USC 102(e).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT B. MONDESI whose telephone number is (571)272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashed Nashaat can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Primary Examiner
Art Unit 1652
April 11, 2008

RBM